REMARKS/ARGUMENTS

Petition is hereby made under the provisions of 37 CFR 1.136(a) for an extension of three months of the period for response to the Office Action. The enclosed cheque includes the prescribed fee.

The Examiner raised several objections to the application:

(a) The quotation made by the Examiner ostensibly from page 5, appears at page 4, line 19 and the appropriate correction has been made.

(b) The quotation made by the Examiner ostensibly from page 21, appears at page 17, line 19 and the appropriate correction has been made.

(c) The Examiner indicated that, while the applicants had identified the trademark Fluzone by the use of the ® symbol, applicants had filed to describe the generic composition of the Fluzone vaccine. The manner of preparation of Fluzone is described on page 11, lines 12 to 20 and in Example 7. There exits, therefore, in the specification a generic identification of the Fluzone influenza virus preparation

It is submitted that the Examiner's objections to the specification have been attended to.

The Examiner rejected claim 3 under 35 USC 112, first paragraph, because the specification, which being enabling for an immunogenic composition comprising an adjuvant wherein there is an enhanced immune response to the claimed composition when compared to the composition of the adjuvant and RSV component without the influenza component which the adjuvant is PCPP and the influenza preparation is Fluzone®, does not reasonably provide enablement for a composition comprising any adjuvant or any influenza preparation with such effects.

Claim 3 has been amended to recite the combination of PCPP and Fluzone. Having regard thereto, it is submitted that claim 3 is fully enabled and hence the rejection thereof under 35 USC 103,112, first paragraph, on these grounds, should be withdrawn.

The Examiner rejected claim 19 under 35 USC 101 in view of the recitation of a use. Claim 19 has been deleted, thereby obviating the rejection.

The Examiner rejected claims 1, 2, 5 to 18 and 20 under 35 USC 103(a) as being obvious over Cates et al USP 6,020,182 (Cates US) in view of Smith et al, US Patent No. 5,762,93 and Webster US Patent No. 5,824,536.

The Cates et al reference is relied on for a teaching of a RSV preparation corresponding to component (a) of the composition of claim 1 and for a teaching of immunostimulation of such composition using an adjuvant. As the Examiner states, the reference indicates, in col. 4, lines 36 to 45, that the immunogenic compositions provided in Cates et al may be formulated to comprise at least one additional immunogen. Among the veritable shopping list of immunogen is mentioned influenza.

There is no motivation to select the influenza from the list of pathogens nor is there any expectation that formulating influenza with the RSV preparation will result in lack of impairment of the immunogenicity of the individual components of the composition.

The Examiner relies on the Smith et al reference for a teaching related to influenza virus vaccine. The Examiner asserts that this disclosure renders obvious the use of non-virulent influenza composition in the composition taught by Cates et al. However, as noted above, there is no motivation to select the influenza virus and no knowledge as to whether or not immunogencities would be impaired, if the Smith et al compositions were used with the Cates et al RSV preparation. Applicants have found that, when a non-virulent influenza virus preparation is selected, then there is no impairment of the respective immunogencities.

While, as the Examiner states, the art of vaccination recognised the value of combining treatments so as to simplify the vaccination process, however, it is equally true that the art of vaccination recognized the potential for impairment of the immunogenicity of one or more of the components of a vaccine containing multiple immunogens. It is not possible to know, in advance, when then such impaired immunogenicity would arise in any new combination of immunogens. The applicants have found that there is no such impairment of immunogenicity when combining the RSV protein preparation with a non-virulent influenza virus preparation.

Although the Examiner included the Webster et al reference in the rejection, there is no discussion of this reference in this rejection. It is, therefore, not possible to comment on the features of the Webster et al reference that might be relied on.

Accordingly, it is submitted that claims 1, 2, 5 to 18 and 20 are patentable over the applied combination of prior art and hence the rejection thereof under 35 USC 103(a) as being unpatentable over Cates et al (Cates US) in view of Smith et al and Webster et al, should be withdrawn.

The Examiner rejected claims 1, 2, 5 to 18 and 20 under 35 USC 103(a) as being unpatentable over Cates et al WO 98/02457 (Cates PCT) in view of Smith et al and Webster et al.

The Cates PCT publication contains the same disclosure as the Cates US patent discussed with respect to the prior art rejection. The rejection, therefore, appears to be merely cumulative of the prior rejection. In any event, the same observations apply to this rejection as to the rejection based on Cates US and the same distinctions also apply.

Accordingly, it is submitted that claims 1, 2, 5 to 18 and 20 are patentable over the applied combination of prior art and hence the rejection thereof

under 35 USC 103(a) as being unpatentable over the Cates PCT in view of Smith et al and Webster et al, should be withdrawn.

The Examiner rejected claims 1, 2, 4, 6 to 14 and 20 under 35 USC 103(a) as being unpatentable over Cates US or Cates PCT as applied to claims 1, 2, 5 to 18 and 20 and further in view of Payne et al. The Cates US and Cates PCT references have been discussed above.

As the Examiner indicates, claim 4 limits the adjuvant of claim 2 to PCPP. As discussed by Payne, PCPP is a known immunoadjuvant. However, applicants rely for the patentability of claim 4 on its dependence on claim 1 and the demonstrated patentability of claim 1 over the disclosures of Cates PCT and Cates US.

Accordingly, it is submitted that claims 1, 2, 4, 6 to 14 and 20 are patentable over the applied art and hence the rejection thereof under 35 USC 103(a) as being unpatentable over Cates US or Cates PCT in view of Payne et al, should be withdrawn.

The Examiner rejected claims 3 and 4 under 35 USC 103(a) as being unpatentable over Cates PCT in view of Andrianov.

As noted above, claim 4 recites PCPP as the adjuvant of claim 1. Claim 3 recites the combination of PCPP as the adjuvant and Fluzone as the non-virulent influenza virus preparation, which imparts an enhanced immune response to RSV when compared to the mixture of RSV immunogens formulated with the adjuvant in the absence of the Fluzone.

The Andrianov reference discloses the use of PCPP as an adjuvant for influenza virus. However, this reference does not remedy the basic defects of Cates PCT with respect to a combination of a non-virulent influenza virus preparation with the mixture of F, G and M RSV proteins, as discussed in detail above. In addition, the reference fails to suggest that, in the presence of Fluzone, PCPP may have an adjuvanting effect on the immune response to the mixture of RSV proteins.

Accordingly, it is submitted that claims 3 and 4 are patentable over the applied combination of prior art and hence the rejection thereof under 35 USC 103(a) as being unpatentable over Cates PCT in view of Andrianov, should be withdrawn.

The Examiner rejected claims 1, 2, 5 to 16 and 20 under 35 USC 103(a) as being unpatentable over Cates US or Cates PCT and further in view of Huebner. Huebner describes the split virus vaccine Fluzone and the processing thereof to obtain intact HA protein and formation of immunogenic conjugates therefrom.

The Huebner reference is no more relevant to the present invention than the Smith et al reference discussed above. For the reason that the Smith et al reference and the Cates US or Cates PCT references cannot be combined, the Huebner reference too cannot be combined with Cates US or Cates PCT.

Accordingly, it is submitted that claims 1, 2, 5 to 10 and 20 are patentable over the applied prior art and hence the rejection thereof under 35 USC 103(a) a being unpatentable over Cates US or Cates PCT and further in view of Huebner, should be withdrawn.

The Examiner rejected claims 20 and 21 under 35 USC 103(a) as being unpatentable over Cates US in view of Smith and Webster or in view of Huebner, and further in view of Murry et al. Claims 20 and 21 are directed to a method of immunizing a host against disease caused by RSV and influenza virus by administering to the host an immunoeffective amount of the composition of claim 1.

The relationships of the combination of Cates US in view of Smith and Webster or in view of Huebner have been discussed above. Murry et al apparently is relied on for a disclosure that RSV infection is a significant pathogen in adults as well as in children. The RSV problem with adults is discussed in the specification on page 1, line 23 to page 2, line 2 and is well known. The applicants do not rely for the

patentability of claims 20 and 21 on any features separate from the distinction that claim 1 have over the prior art, as discussed in detail above.

Accordingly, it is submitted that claims 20 and 21 are patentable over the prior art and hence the rejection of claims 20 and 21 under 35 USC 103(a) as being unpatentable over Cates US in view of Smith and Webster or in view of Huebner, and further in view of Murry et al, should be withdrawn.

The Examiner rejected claims 20 and 21 under 35 USC 103(a) as being unpatentable over Cates US or Cates PCT in view of Smith and Webster, or in view of Huebner and further in view of Potash. The subject matter of claims 20 and 21 has been discussed above.

The Potash reference apparently is relied on for a disclosure that RSV and influenza virus infections may occur throughout the adult life of a person. However, as noted above, the patentability of claims 20 and 21 relies on the patentability of claim 1 over the applied combinations of prior art for the reasons discussed above.

Accordingly, it is submitted that claims 20 and 21 are patentable over the applied art and hence the rejection thereof under 35 USC 103(a) as being unpatentable over Cates US or Cates PCT in view of Smith and Webster or in view of Huebner, and further in view of Potash, should be withdrawn.

The Examiner rejected claims 20 and 21 under 35 USC 103(a) as being unpatentable over Cates US in view of Smith and Webster, or in view of Huebner, and further in view of Hall et al, Crowe, Groothuis and Falsey for statement concerning the efficacy of RSV subunit vaccines in children and adults. These statements do not remedy the basis defect of the basic combination of prior art, for the reasons already discussed.

As further discussed above, the applicants rely for the patentability of claims 20 and 21 on the patentability of claim 1 over the basic combination of prior art. Accordingly, it is submitted that claims 20 and 21 are patentable over the applied

prior art and hence the rejection thereof under 35 USC 103(a) as being unpatentable over Cates US in view of Smith and Webster or in view of Huebner and further in view of Hall et al, Crowe, Groothuis and Falsey, should be withdrawn.

The Examiner rejected claims 1, 2, 4 and 6 to 21 under 35 USC 103(a) as being obvious over claims 1 to 9, 13, 15 to 21, 23 and 26 of commonly-assigned No. 09/950,655 in view of Smith, Webster, Payne and Murry.

As the Examiner states, this application and Application No. 09/950,655 are commonly owned. The subject matter claimed in the claims of 09/950,655 to which the Examiner refers is the same as already discussed with respect to the Cates US and Cates PCT references. The Examiner's attention is directed to that discussion and the discussion of the combination of the disclosures with Smith, Webster, Payne and Murry.

Accordingly, it is submitted that claims 1, 2, 4 and 6 to 21 are patentable over the applied combination of prior art and hence the rejection thereof under 35 USC 103(a) as being unpatentable over copending Application No. 09/950,655 in view of Smith, Webster, Payne and Murry, should be withdrawn.

The Examiner considered that claims 1, 2, 4 and 6 to 21 are directed to an invention not patentably distinct from claims 1 to 9, 13, 15 to 21, 23 and 26 of commonly-assigned copending Application No. 09/950,655.

As the Examiner correctly observes, applicants claims specifically require the use of an immunoeffective amount of a non-virulent influenza virus preparation with the mixture of RSV proteins. Even though claim 21 of the Application No. 09/950,655 refers to the potential presence of at least additional immunogen, there is no specific claim to a non-virulent influenza virus preparation as specifically required by applicants claims. In addition, claim 1 requires that the immunogenic composition is formulated as a vaccine for *in vivo* administration to a host wherein the individual components (a) and (b) of the composition are formulated with that the immunogenicity of the individual components (a) and (b) is

not impaired. It is submitted that these two features of claim 1 of this application patentably distinguish the claims of this application from those of copending Application No. 09/950,655.

Accordingly, it is submitted that claims 1, 2, 4 and 6 to 21 are patentably distinct from claims 1 to 9, 13, 15 to 21, 23 and 26 of commonly-assigned copending Application No. 09/950,655 and hence the rejection should be withdrawn.

The Examiner provisionally rejected claims 1 to 10, 12 to 16, 20 and 21 under 35 USC 101 as claiming the same invention as that claims 1, 3 to 11, 13 to 18 and 20 of copending Application No. 09/213,770. The rejection is a provisional one, since the conflicting claims are not in fact been patented. No action, therefore, is required at the present time with respect to this matter.

The Examiner rejected claims 1, 2 and 5 to 21 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 6 to 16 of US Patent No. 6,309,649 in view of Smith or Palese.

US Patent No. 6,309,649 is a cip of the Cates US patent discussed above. It is submitted that the reference contains no more relevant prior art than the Cates US reference and hence the comments made above with respect thereto and the combination with Smith apply equally to this rejection.

Palese apparently is relied on for the teaching of attenuated influenza virus and its utility in vaccines. As such, the Palese reference appears to be no more relevant than the Smith reference, discussed above.

Accordingly, it is submitted that claims 1, 2 and 5 to 21 are patentably distinct from the claims of USP 6,309,649 and hence the rejection thereof under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 6 to 11 of US Patent No. 6,309,649 in view of Smith et al or Palese.

The Examiner provisionally rejected claims 1, 11, 15 and 17 to 19 under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3 to 11, 13 to 18 and 20 of copending Application No. 09/213,770, or over those claims in view of Smith or Palese.

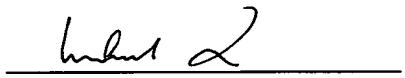
As the Examiner notes, the rejection is a provisional one because the conflicting claims have not in fact been patented. No action, therefore, is required at the present time with respect to this rejection.

The Examiner provisionally rejected claims 1, 2, 4 and 6 to 21 under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 9, 13, 15 to 21, 23 and 26 of copending Application No. 09/950,655 in view of Smith, Webster, Payne and Murry.

As the Examiner notes, the rejection is a provisional one because the conflicting claims have not in fact been patented. No action, therefore, is required at the present time with respect to this rejection.

It is believed that this application is now in condition for allowance and early and favourable consideration and allowance are respectfully solicited.

Respectfully submitted,



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